

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
Richard M. Chesbrough, et al.) Group: 3768
Serial No.: 10/707,043)
Filed: November 17, 2003)
Title: APPARATUS AND METHOD FOR IMPLANTING)
A PRELOADED LOCALIZATION WIRE) Examiner: E. Weatherby

ATTACHMENT TO PRE-APPEAL BRIEF REQUEST FOR REVIEW

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby submit this Attachment to their Pre-Appeal Brief Request for Review.

REMARKS

Claims 1-4, 6-47 and 49-75 are pending in the present patent application and stand rejected.

Appellants believe that the rejection of claims 1-4, 6-47 and 49-75 is clearly in error.

Claims 1-4, 6-26, 30-43, 47 and 49-75 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication No. 2001/0034528 (Foerster) in view of U.S. Patent No. 6,090,063 (Makower).

Appellants respectfully submit that all of the limitations of claim 1 are not found in the cited references, taken alone or in combination, and thus a *prima facie* case of obviousness has not been established. “To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Claim 1 is directed to an apparatus for percutaneously implanting a localization wire within a tissue mass, in part reciting:

...a cannula defining a lumen and having a distal end forming an insertion tip; a localization wire located within the lumen and having a distal end near the insertion tip when the cannula is in the insertion position, wherein the localization wire comprises at least one anchor adapted to hold the localization wire in the tissue mass; and an actuator in operable communication with the cannula and operable between a charged condition and a discharged condition to retract the cannula to expose the distal end of the localization wire to the tissue mass. (Emphasis added).

Foerster discloses a marking instrument 10 which carries marker element 12 including an umbrella end comprising a pair of attachment members 14, 16 attached to center wire 18. An outer piercing needle (cannula) 38 having piercing tip 40 is used to insert marker element 12 at the desired location. (Para. [0042] – [0043]; Figs. 1, 2 and 5-6A). Note, in Foerster, the marking instrument 10 does not include the piercing tip 40, but rather the hollow outer piercing cannula 38 into which tube 54 of marking instrument 10 is positioned. (Fig. 1). Thus, in Foerster the cannula 38 having the insertion tip is stationary during marker deployment in the tissue mass.

Makower discloses a filament injection device 1 including conduit (insertion needle) 6 which serves as a delivery cannula having an insertion tip, as illustrated in Fig. 1. Because of the need to minimize the diameter of distal end 12 of filament injection device 1, the bulkier suture feeding mechanism, which feeds the flaccid filament 5 into conduit 6, resides in the housing 7 of the device 1. (Col. 8, ll 21-35). Note, in Makower, it is the conduit (insertion cannula) 6 that includes the piercing tip (Fig. 1), and the cannulas 14, 15 of the feeding mechanism are not configured to include an insertion tip. (Figs. 4A, B). Thus, in Makower the cannula 6 having the insertion tip is stationary during deployment of the filament 5 in the tissue mass.

In contrast to Foerster and Makower wherein the cannula having the insertion tip is stationary, the apparatus of claim 1 is configured such that the cannula having the insertion tip is operable between a charged condition and a discharged condition to retract the cannula to expose the distal end of the localization wire to the tissue mass.

Further, the apparatus of claim 1 includes an actuator in operable communication with the cannula, the actuator operable between a **charged** (extended) condition and a **discharged** (retracted) condition to retract the cannula and expose the distal end of the localization wire to the tissue mass. In contrast, in Foerster the marker element 12 is exposed to the tissue mass prior to and during insertion **without retracting** cannula tube 54. Also, in Makower it is the **advancement** (not retraction) of the inner cannula 14 that discharges the flaccid filament 5 to expose the distal end of filament 5 to the tissue mass, and the retraction of inner cannula 14 is to reset the inner cannula 14 relative to the flaccid filament 5 for the next advancement.

Accordingly, a *prima facie* case of obviousness has not been established since Foerster and Makower, taken alone or in combination, do not disclose, teach or suggest all limitations of claim 1. Therefore, claim 1 is allowable in its present form.

As a further point of argument, Foerster requires cannula tube 54 to be stationary relative to marker element 12 during marker deployment such that exposed attachment members 14, 16 are

pulled against the end of cannula tube 54 as center wire 18 is pulled by pull ring 24. (See, Foerster, Figs. 5-6A). In contrast to Foerster, Makower *requires* inner cannula 14 carrying flaccid filament 5 to be *movable* to linearly reciprocate relative to filament 5 such that during advancement of filament 5 by the action of actuator mechanism 502 of actuating pad 17, both inner cannula 14 and filament 5 are advanced equal to the distance 19 of motion that actuating pad 17 is urged, and the retraction of distal segment 408 of inner cannula 14 is achieved by means of the force supplied by containment spring 412 in compression. Thus, the Examiner's asserted combination of Foerster and Makower would render each other inoperable, since in Foerster cannula tube 54 is required to be stationary during marker deployment, while in Makower inner cannula 14 is required to move to deploy the filament 5.

Accordingly, Appellants respectfully submit that one skilled in the art would not be motivated to combine Foerster with Makower in an attempt to achieve the invention as recited in Appellants' claim 1. In essence, to attempt the combination would be tantamount to impermissible hindsight reconstruction of Appellants' claim 1.

Thus, for this additional reason claim 1 is allowable in its present form.

Claims 2-4, 6-26 and 30-35 depend from claim 1 and, thus, are allowable for at least the reasons set forth above with respect to claim 1.

In addition, claims 2-4, 6-26 and 30-35 further and patentably define the invention over the cited references.

For example, claim 19 recites, "The apparatus of claim 18 wherein the biasing element is a spring in operable communication with the trigger such that movement of the trigger from the ready position to the release position *releases the spring from a compressed state to an expanded state to move the cannula from the insertion position to the implant position.*" (Emphasis added). In contrast, Foerster does not disclose a biasing element and Makower discloses that the feeding action allows a high force per unit cross-sectional area to be applied in advancing flaccid filament 5 into the body tissue while a lower force is supplied by containment spring 412 to retract the distal segment 408 of inner cannula 14. (Col. 9, ll 21-29; Figs 4A, 4B). Accordingly, for these additional reasons, claim 19 is allowable in its own right.

Claim 36 recites in part:

...a cannula defining a lumen and having a distal end forming an insertion tip; a localization wire located within the lumen and having a distal end near the insertion tip when the cannula is in the insertion position, wherein the localization wire comprises at least one anchor adapted to hold the localization

wire in the tissue mass; and an actuator operable between a charged condition and a discharged condition to effect movement of the cannula relative to the localization wire to expose the localization wire to the surrounding tissue mass at the distal end of the cannula; wherein the handle, the cannula, the localization wire, and the actuator form a self-contained implanting apparatus for implanting the localization wire into the tissue mass, whereby the cannula is inserted into the tissue mass and the actuator is placed in the discharged condition to effect movement of the cannula relative to localization wire to expose the distal end of the localization wire to the tissue mass. (Emphasis added).

Accordingly, claim 36 is allowable for substantially the same reasons set forth above with respect to claim 1.

Claims 37-43, 47 and 49-59 depend from claim 36, and thus are allowable for at least the same reasons set forth above with respect to claim 1 as applied to claim 36.

In addition, claims 37-43, 47 and 49-59 further and patentably define the invention over the cited references. For example, claim 41 recites, “The apparatus of claim 40 wherein the biasing element is a spring operably coupled to the trigger such that movement of the trigger from the ready position to the release position releases the spring from a compressed state to an expanded state to move the cannula from the insertion position to the implant position.” Accordingly, claim 41 is allowable in its own right for substantially the same reasons set forth above with respect to claim 19.

Claim 60 recites in part,

...a cannula defining a lumen and having a distal end forming an insertion tip; a localization wire pre-loaded within the lumen and having a distal end near the insertion tip; and an actuator connected to the cannula and operable between a charged condition and a discharged condition to effect relative movement of the cannula and the localization wire to expose the distal end of the localizing wire; inserting the insertion tip of the cannula and the localization wire into the tissue mass; and operating the actuator to retract the cannula to expose a portion of the distal end of the localization wire to the tissue mass. (Emphasis added).

Claim 60 is allowable for substantially the same reasons set forth above with respect to claim 1. Claims 61-75 depend from claim 60 and, thus, are allowable for at least the same reasons set forth above with respect to claim 1 as applied to claim 60.

Accordingly, for at least the reasons set forth above, it is respectfully submitted that claims 1-4, 6-26, 30-43, 47 and 49-75 are patentable under 35 U.S.C. §103(a) over Foerster in view of Makower, and it is respectfully requested that the rejection of claims 1-4, 6-26, 30-43, 47 and 49-75 under 35 U.S.C. §103(a) as being unpatentable over Foerster in view of Makower be reversed.

Claims 27-29 and 44-46 were rejected under 35 U.S.C. §103(a) as being unpatentable over Foerster in view of Makower as applied to claim 25, and further in view of U.S. Patent No. 6,813,520 (Truckai). However, claims 27-29 and 44-46 are allowable at least in view of their respective dependence from base claims 1 and 36, since Truckai does not overcome the deficiencies of Foerster and Makower with respect to claims 1 and 36.

Accordingly, it is respectfully submitted that claims 27-29 and 44-46 are patentable over Foerster in view of Makower, and further in view of Truckai, under 35 U.S.C. §103(a), and it is respectfully requested that the rejection of claims 27-29 and 44-46 under 35 U.S.C. §103(a) as being unpatentable over Foerster and Makower, and further in view of Truckai, be reversed.

For at least the foregoing reasons, Appellants respectfully request reversal of all rejections and allowance of the claims.

In the event Appellants have overlooked the need for an extension of time, an additional extension of time, payment of fee, or additional payment of fee, Appellants hereby conditionally petition therefor and authorize that any charges be made to Deposit Account No. 20-0095, TAYLOR & AUST, P.C.

Should any question concerning any of the foregoing arise, the undersigned may be reached by telephone at (317) 894-0801.

Respectfully submitted,

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